

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE: NATIONAL PRESCRIPTION</b>	)	<b>MDL 2804</b>
<b>OPIATE LITIGATION</b>	)	
	)	<b>Case No. 1:17-md-2804</b>
<b>THIS DOCUMENT RELATES TO:</b>	)	
	)	<b>Judge Dan Aaron Polster</b>
<i>The Montgomery County Board of County</i>	)	
<i>Commissioners, et al. v. Cardinal Health,</i>	)	<b><u>OPINION AND ORDER RE:</u></b>
<i>Inc., et al., Case No. 1:180-op-46326</i>	)	<b><u>KROGER'S MOTION TO EXCLUDE</u></b>
<i>("Track Seven")</i>	)	<b><u>PORTIONS OF OPINIONS OF DR.</u></b>
	)	<b><u>ANNA LEMBKE, DAVID</u></b>
	)	<b><u>COURTWRIGHT, AND JAMES</u></b>
	)	<b><u>RAFALSKI</u></b>

Before the Court is Kroger's Motion to Exclude Portions of the Opinions Offered by Dr. Anna Lembke, David Courtwright, and James Rafalski (docket no. 4889).<sup>1</sup> Plaintiff Montgomery County filed a response (docket no. 4946) and Kroger filed a reply (docket no. 4964). For the reasons stated below, Kroger's Motion is **GRANTED in part** with respect to part of Lembke's sixth opinion, and is otherwise **DENIED**.

**Introduction**

Kroger asks the Court to exclude portions of the expert opinions offered by Dr. Anna Lembke, David Courtwright, and James Rafalski "to the extent they violate Orders previously entered by the Court in prior MDL tracks." Motion at 1 (docket no. 4889). This Court has ruled

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<sup>1</sup> The motion was filed by The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II (collectively, "Kroger").

that “all of the Court’s Orders and rulings entered in other case tracks of this MDL . . . shall apply to and control this *Case Track 7* . . . unless a party bound by such Order or ruling shows good cause why it should not apply.” CT7 Order Regarding Previously Decided Issues at 3 (docket no. 4978).

Kroger asserts the Court’s prior rulings establish that: (1) Lembke is not qualified to express opinions regarding the causal effect of Defendants’ pharmaceutical marketing on opioid prescribing or supply, or that Kroger failed to provide its pharmacists with sufficient time, resources, or incentives to investigate “red flags” (*i.e.*, warning signals that pharmacies could use to identify potentially illegitimate prescriptions); (2) Courtwright is not qualified to express marketing causation opinions; and (3) Rafalski may not offer legal opinions stated in Section III.L of his *Track 7* Report. As set forth below, the Court agrees that its prior rulings preclude Lembke from opining that Kroger failed to provide its pharmacists with sufficient time, resources, or incentives to investigate “red flags.” However, Kroger has not shown the Court’s prior rulings prevent the experts from offering the other challenged opinions.

## **I. Legal Standards.**

The Court incorporates by reference the applicable *Daubert* legal standards set forth in its *Track One Daubert Order re: Rosenthal* (docket no. 2495 at 1-10).<sup>2</sup>

## **II. Dr. Anna Lembke**

Anna Lembke, M.D., is a highly distinguished medical doctor and professor with expertise in psychiatry, addiction, and pain medicine. In *Track 7*, Lembke offers opinions on a broad range

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<sup>2</sup> *In re Nat’l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 3934597, at \*1-5 (N.D. Ohio Aug. 20, 2019).

of topics, including: addiction; the history of opioid marketing and prescribing; and Defendants' role in the opioid epidemic, focusing on their marketing and dispensing practices. *See* CT7 Lembke Report at 9-11 (docket no. 4889-1) (summarizing Lembke's opinions in 15 numbered paragraphs).

Citing the Court's prior *Daubert* rulings in *Track 1* and *Track 3*, Kroger asserts Lembke may not express all or part of her fourth and sixth opinions. In relevant part, these opinions state:

4. The Pharmaceutical Opioid Industry contributed substantially to the paradigm shift in opioid prescribing through misleading messaging about the safety and efficacy of prescription opioids. . . .

\* \* \*

6. Pharmacies leveraged their unique and pivotal position in the opioid supply chain to contribute to the unprecedented and unchecked flow of opioid pain pills into the community. . . . They ignored 'red flags' for misuse and diversion (including concerns expressed by their own pharmacists), and failed to provide pharmacists with sufficient time, resources, or incentives to investigate red flags. They also failed to use or analyze their own dispensing data to assist pharmacies in identifying red flags. By increasing and assuring the supply of opioids, and failing to provide effective controls against diversion, pharmacies contributed to opioid misuse, addiction, dependence, and death.

CT7 Lembke Report at 9-10 (docket no. 4889-1). Additionally, Kroger seeks to exclude all or part of Lembke's detailed statements supporting these opinions. *See id.* at 27-91 (detailed statements supporting the fourth opinion); *id.* at 100-207 (detailed statements supporting the sixth opinion).

#### **A. Opinion #4 – Marketing Causation**

As noted, in her fourth opinion, Lembke states the pharmaceutical opioid industry "contributed substantially to the paradigm shift in opioid prescribing through misleading messages about the safety and efficacy of prescription opioids." CT7 Lembke Report at 9-10 (docket no. 4889-1). Kroger seeks to exclude the entirety of this opinion, including 64 pages of detailed supporting statements,<sup>3</sup> based on the Court's *Track 1* and *Track 3 Daubert* rulings.

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<sup>3</sup> The detailed statements supporting the fourth opinion cover a broad range of topics, including: (1) studies, conclusions, and findings by others (including the National Academies of Sciences, Engineering and Medicine and

### 1. Prior *Daubert* Rulings

In *Track 1*, the Court found Lembke was “fully qualified” to opine on matters involving medical facts and science falling within the areas of psychiatry, addiction, and pain – including her opinions on the inaccuracy of statements and representations made in Defendants’ promotional and educational materials, and how doctors generally rely on such information in making prescribing decisions. CT1 Daubert Order re: Marketing Causation at 12-13 (docket no. 2549).<sup>4</sup> The Court found, however, that plaintiffs had not shown Lembke was qualified to testify as an expert on the topic of marketing causation. *Id.* The Court therefore ruled that Lembke could not offer opinions regarding the *causal effect* of Defendants’ actions on doctors’ prescribing practices – that is, she could not opine that “Defendants’ marketing efforts resulted in increased sales and/or increased supply of prescription opioids.” *Id.* at 12.

In *Track 3*, plaintiffs asked the Court to revisit its *Track 1* ruling based on “substantial new or additional evidence” that purportedly showed Lembke had expanded her field of expertise in the intervening years.<sup>5</sup> CT3 Daubert Order re: Lembke at 6-7 (docket no. 3953) (citations omitted).<sup>6</sup> The Court declined to revisit or alter its *Track 1* ruling, stating: “At the time of its [*Track*

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the Stanford-*Lancet* Commission) stating aggressive opioid marketing tactics sparked a massive increase in opioid prescribing, *id.* at 27-31; (2) examples of aggressive marketing efforts by pharmaceutical companies including Endo, Actavis/Allergan, Watson Pharma, Janssen, and TEVA/Cephalon, *id.* at 31-52; (3) opioid manufacturers’ support of key opinion leaders to encourage doctors to prescribe more opioids based on misleading information, *id.* at 52-63; (4) pharmaceutical companies’ influence on medical school curricula, continuing medical education, medical literature, clinical decision support tools, professional medical societies, patient advocacy groups, and other organizations, *id.* at 63-85; and (5) examples of misrepresentations in promotional materials regarding “pseudoaddiction” and “breakthrough pain,” *id.* at 86-91.

<sup>4</sup> *In re Nat’l Prescription Opiate Litig.*, 2019 WL 4054998 (N.D. Ohio Aug. 28, 2019).

<sup>5</sup> Specifically, plaintiffs cited a lecture given by Lembke at Duke University in 2020 on the topic of “market-driven epidemics,” and a new paragraph in her Report detailing her teaching on marketing of opioids and its impact on the prescribing habits of physicians. *See* CT3 Daubert Order re: Lembke at 6-7 (docket no. 3953).

<sup>6</sup> *In re Nat’l Prescription Opiate Litig.*, 2021 WL 4243084 (N.D. Ohio Sept. 17, 2021).

I] ruling on Lembke, the Court was aware of her expertise in opioid marketing, which is why it allowed her to testify, within limits, on that subject.” *Id.*

## 2. *Track 3* Trial Testimony

In the *Track 3* trial, Lembke testified that the pharmacy defendants (CVS, Walgreens, and Walmart) engaged in coordinated efforts with opioid manufacturers and distributors to disseminate misleading promotional marketing and educational materials. Lembke opined that these materials and related activities are “well-known and effective strategies for influencing what medicine gets prescribed, creating the demand for a specific medication.”<sup>7</sup> Further, Lembke opined these misleading promotional efforts “substantially contributed” to the opioid epidemic by creating “a radical paradigm shift” in increased opioid prescribing, thereby creating an oversupply of prescription opioids.<sup>8</sup> Lembke explained the misleading promotional efforts resulted in

a complete and radical reeducation of doctors and other health care professionals and a shift in the way that doctors prescribed opioids, such that they prescribed more of them, more often, and for minor and chronic pain conditions at ever-escalating doses because they were taught that no dose is too high. *And that essentially is what led to the current U.S. opioid epidemic.*

10/06/21 CT3 Trial Tr. at 548:22-549:6 (docket no. 4000) (emphasis added); *see also id.* at 546:4-14.

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<sup>7</sup> More specifically, Lemke testified:

There have been a lot of studies . . . [that] consistently show . . . when you engage in what’s called direct-to-consumer advertising in any form, you promote a specific brand of a medication to a patient, that patient is more likely to ask for that medication. Likewise, direct-to-prescriber promotional efforts result in the prescriber being more likely to prescribe that medication. So these are well-known and effective strategies for influencing what medicine gets prescribed, creating the demand for a specific medication.

10/06/21 CT3 Trial Tr. at 586:6-17 (docket no. 4000); *see id.* at 578-598, 608-616.

<sup>8</sup> 10/06/21 CT3 Trial Tr. at 515-521, 545-558, 582-598 (docket no. 4000).

The *Track 3* defendants did not object to Lembke's testimony at trial. However, they later sought judgment as a matter of law, arguing, *inter alia*, that Lembke's trial testimony extended "far beyond her expertise and qualifications." CT3 Order Denying JMOL at 58 (docket no. 4295) (citation omitted).<sup>10</sup> The Court denied the motion, finding the *Track 3* defendants had waived their right to raise this objection by not doing so at trial. *Id.* at 61. Further, the Court found that, even if the *Track 3* defendants had objected at trial, it would have allowed the testimony. *Id.* at 61-62. The Court concluded: "In light of Lembke's distinguished academic background on opioid prescribing and the history and origins of the opioid epidemic, combined with her first-hand experiences as a practicing physician during the relevant time frame, Lembke's testimony on these topics was well within the scope of her extensive medical knowledge and expertise. . . . [and] was properly received into evidence at trial."<sup>11</sup> *Id.* at 62.

### 3. Analysis

Kroger asserts Lembke's fourth opinion contains numerous marketing causation conclusions that are "specifically excluded" under the Court's prior *Daubert* rulings. These conclusions include: (1) the pharmaceutical opioid industry's misleading marketing "contributed substantially" to a "paradigm shift in opioid prescribing;" (2) due to the industry's "aggressive and misleading promotion, opioids were prescribed in abundance;" (3) these misleading marketing methods "directly contributed to the opioid epidemic;" (4) the pharmaceutical opioid industry engaged an aggressive sales force to target doctor's offices and pharmacies "to increase sales,

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<sup>10</sup> *In re Nat'l Prescription Opiate Litig.*, 589 F.Supp.3d 790, 828 (N.D. Ohio 2022).

<sup>11</sup> In reaching this result, the Court noted that Lembke's *Track 3* testimony "conceivably extended" beyond the lines the Court had drawn in its *Track 1 Daubert* ruling. CT3 Order Denying JMOL at 62 n.159 (docket no. 4295). Nonetheless, the Court concluded Lembke did not testify outside of her area of expertise.

thereby increasing the number of people exposed to opioids;” and (5) certain evidence “makes it clear that promotion of opioids to prescribers and their staff is a highly effective strategy for increasing opioid sales.” Motion at 3-4 (docket no. 4889) (quoting CT7 Lembke Report at 27-29, 51).

Plaintiff responds that Kroger’s request to strike *all* of the detailed statements supporting Lembke’s fourth opinion is overbroad. Plaintiff asserts that, at most, the Court’s prior rulings preclude only those statements “that purport to find Defendants’ marketing efforts resulted in or caused increased sales and/or increased prescriptions of opioids.” Response at 9 (docket no. 4946) (quoting CT1 Daubert Order re: Marketing Causation at 12 (docket no. 2549)). Further, Plaintiff asks the Court to depart from its prior rulings and allow Lembke to offer “previous excluded opinions on marketing causation,” based on “new evidence” of her expanded expertise – that is, some of her recent presentations and scholarly work. Response at 6, 12 (docket no. 4946).

Curiously, in their briefing, neither side mentions Lembke’s actual *Track 3* trial testimony, or the Court’s post-trial rulings regarding that testimony. In the *Track 3* trial, Lembke expressed opinions on marketing causation very similar to the ones Kroger now seeks to exclude. Lembke testified, *inter alia*, that: (1) opioid manufacturers, distributors, and pharmacies engaged in misleading promotional activities that are “well-known and effective strategies for influencing what medicine gets prescribed [and] creating the demand for a specific medication;” and (2) these efforts “contributed substantially” to a “paradigm shift” in increased prescribing, thereby creating an oversupply of prescription opioids. CT3 Order Denying JMOL at 61-62 (docket no. 4295) (quotations and citations omitted). This testimony mirrors the same opinions that Kroger now challenges. *See* Motion at 3-4 (docket no. 4889) (seeking to exclude Lembke’s opinions that misleading marketing activities “contributed substantially” to the opioid epidemic by creating a

“paradigm shift” in prescribing and causing opioids to be “prescribed in abundance”) (citations and quotations omitted).

In post-trial rulings, the Court found that Lembke’s *Track 3* trial testimony was “well within the scope of her extensive medical knowledge and expertise,” given her “distinguished academic background on opioid prescribing and the history and origins of the opioid epidemic, combined with her first-hand experiences as a practicing physician during the relevant time frame.” CT3 Order Denying JMOL at 62 (docket no. 4295). Based on the Court’s first-hand observation and in-depth evaluation of Lembke’s courtroom testimony in *Track 3*, the Court reaffirms that ruling here. Put simply, Lembke has sufficient experience, knowledge, and expertise to offer all of the statements she made in the *Track 3* trial.

Plaintiff asks the Court to modify its prior rulings based on “new evidence” regarding Lembke’s recent presentations and scholarly work. Response at 12 (docket no. 4946). It is unclear to what extent Plaintiff seeks to expand the scope of Lembke’s recognized expertise beyond that of her *Track 3* trial testimony, or whether any such expansion is necessary to allow her to make certain challenged statements.<sup>13</sup> Regardless, the Court declines to do so based on the “new evidence” of Lembke’s expertise.

Plaintiff asserts this “new evidence” shows that “governments and academics alike recognize Lembke’s qualification to speak on the causes of the opioid epidemic, including the

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<sup>13</sup> As discussed, in its response, Plaintiff contends that, at most, the Court’s prior *Daubert* rulings preclude Lembke from drawing a causal connection between marketing and prescribing habits or supply of prescription opioids. *See* Response at 9. But the response fails to mention, and apparently overlooks, that: (1) Lembke testified to this causal connection in *Track 3* (by stating misleading promotional efforts “substantially contributed” to the opioid epidemic by increasing prescribing and creating an oversupply of prescription opioids); and (2) the Court ruled, post-trial, that this testimony was “well within the scope of her extensive medical knowledge and expertise.” CT3 Order Denying JMOL at 61-62 (docket no. 4295). Given this apparent oversight in the briefing, it is unclear whether Plaintiff is asking the Court to expand the scope of Lembke’s recognized expertise beyond that of her *Track 3* testimony. In any event, at least some of what Plaintiff now asks has already been permitted, and the Court declines to expand the scope of Lembke’s allowed testimony further.



pharmaceutical industry’s marketing.” Response at 12 (docket no. 4946). Plaintiff points to: (1) Lembke’s recent service as a member of the Stanford-*Lancet* Commission on the North American opioid crisis; and (2) two recent presentations given by Lembke regarding the opioid crisis. *Id.* at 12-13. Plaintiff contends this evidence demonstrates “Lembke is an acknowledged expert on the causes of the opioid epidemic, including on the causal role of the industry’s false and misleading promotional activities.” Response at 13-14 (docket no. 4946). The Court does not necessarily disagree with this statement; however, the “new evidence” cited by Plaintiff does not demonstrate that Lembke’s expertise extends beyond the scope of her *Track 3* testimony.<sup>14</sup>

Plaintiff asserts Lembke’s service on the Stanford-*Lancet* Commission establishes she is qualified to opine fully on marketing causation. On February 2, 2022, the Stanford-*Lancet* Commission published a Report that lists 17 authors, including Lembke. *See* Responding to the Opioid Crisis in North America and Beyond: Recommendations of the Stanford-*Lancet* Commission, *The Lancet*, Vol. 399 at 555 (Feb. 5, 2022) (“Stanford-*Lancet* Report”).<sup>16</sup> According to the Report, “[t]he Commission is supported by Stanford University and brings together diverse Stanford scholars and other leading experts across the USA and Canada, with the goals of understanding the opioid crisis, proposing solutions to the crisis domestically, and attempting to stop its spread internationally.” *Id.* The Report further states, *inter alia*, that the Commission is: (1) comprised of experts in the areas of “addiction medicine, biochemistry, emergency medicine, epidemiology, health economics, internal medicine, law, pain medicine, policy analysis,

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<sup>14</sup> Plaintiff asserts this “new evidence” was presented, on remand, in *Case Track 4*, to the Honorable Charles R. Breyer, who found “Lembke was qualified to opine on the effects of Defendants’ marketing practices.” Response at 14 (docket no. 4946) (citing Order re *Daubert* Motions, Doc. #1297 in N.D. Calif. Case No. 18-cv-07591). Judge Breyer’s order does not indicate what evidence he reviewed, or whether he found Lembke’s expertise extended beyond the scope of her *Track 3* trial testimony. *See id.* Accordingly, the *Track 4* order is unhelpful here.

<sup>16</sup> The Stanford-*Lancet* Report is available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02252-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02252-2/fulltext) (last checked 05/02/2023).

psychiatry, pharmacology, and public health,” *id.* at 564; and (2) “focused on developing a coherent, empirically grounded analysis of the causes of, and solutions, to the opioid crisis,” *id.* at 555.

In her *Track 7* Report, Lembke states that, as one of 18 members of the Commission, she co-authored the *Stanford-Lancet* Report, which specifically identifies and describes the pharmaceutical industry’s marketing and promotional conduct as “a cause” of the opioid epidemic. CT7 Lembke Report at 5 (Doc. #: 4889-1). Lembke further states she “participated actively in all aspects of the preparation of the peer-reviewed Commission Report.” *Id.*

That Lembke served as one of many experts on this Commission, however, does not show she has gained additional specialized training or experience regarding the effect of pharmaceutical marketing on prescribing habits or the supply of prescription opioids. Stated differently, the fact that Lembke is one of many co-authors of the Report does not show that she is an expert on *every aspect* of the Report. This Court has already recognized Lembke’s expertise in the areas of psychiatry, addiction, and pain medicine, based on her background and experience. Further, the Court has found that Lembke is qualified to opine, to some extent, on the causal effect of pharmaceutical opioid promotional activities, *i.e.* within the parameters of her *Track 3* trial testimony. Plaintiff has not shown that Lembke’s service on *Stanford-Lancet* Commission has somehow greatly expanded her expertise to testify in this regard.

Plaintiff also asserts that two recent presentations given by Lembke in 2022 demonstrate she is an expert on the “causes” and “origins” of the opioid epidemic. Response at 13 (docket no. 4946). Plaintiff cites an invitation extended by the “Science and Law” initiative at the American Association for the Advancement of Science, in conjunction with the Administrative Office of Kentucky Courts, that recognized Lembke’s “expertise” and asked her to give a 25-minute

presentation “on the background (e.g., origins, sociology, current status) of the opioid crisis.”<sup>18</sup> CT7 Lembke Report at 6 (docket no. 4889-1); *see* Response at 13 (docket no. 4946). Plaintiff also cites a “similar presentation” Lembke gave to elected representatives in Edmonton, Canada, at the invitation of the Ministerial Assistant to the Associate-Minister of Mental Health and Addictions. *Id.* As discussed, this Court has already recognized that Lembke has some level of expertise in opioid marketing, “which is why it allowed her to testify, within limits, on that subject.” CT3 Daubert Order re: Lembke at 7 (Doc. #: 3953). But that Lembke may have expressed opinions on marketing causation in recent presentations does not show her expertise in this area has expanded beyond the scope of her *Track 3* trial testimony.

Accordingly, the Court holds that Lembke may generally testify in *Track 7* along the same lines as her testimony in the *Track 3* trial. In the context of trial, Kroger may object if any specific testimony proffered by Lembke extends further than these parameters.<sup>19</sup>

## **B. Opinion #6 – Dispensing Practices**

In her sixth opinion, Lembke describes how pharmacies “leveraged their unique and pivotal position in the opioid supply chain to contribute to the unprecedented and unchecked flow of

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<sup>18</sup> According to Lembke, her PowerPoint for this presentation included slides outlining the myths promoted by the pharmaceutical industry, including misleading messages identical to those stated in her *Track 7* Report. CT7 Lembke Report at 6 (docket no. 4889-1).

<sup>19</sup> The Court cautions that Lembke (like any expert) must stop short of offering opinions that impermissibly tell the jury what result to reach or attempt to quantify a particular contribution without accounting for other possible causes or confounding factors. *See, e.g.*, CT3 Daubert Order re Rafalski at 13-14 (docket no. 3929) (expert’s opinion that Defendants’ SOMS failure was a “substantial cause” of the opioid epidemic impermissibly embraced an ultimate legal issue that was for the jury’s determination); *Berry v. City of Detroit*, 25 F.3d 1342, 1353-54 (6th Cir. 1994) (an expert may not opine as to the ultimate question of liability; rather, an expert may only state an opinion “that suggests the answer to the ultimate issue or that gives the jury all the information from which it can draw inferences as to the ultimate issue”).

opioid pain pills into the community.”<sup>25</sup> CT7 Lembke Report at 100 (docket no. 4889-1). As part of this opinion, Lembke states the pharmacies “ignored ‘red flags’ for misuse and diversion (including concerns expressed by their own pharmacists), *and failed to provide pharmacies with sufficient time, resources or incentives to investigate red flags.*” *Id.* (emphasis added). Kroger asserts the italicized portion of this statement expresses exactly the same opinion that this Court previously excluded in its *Track 3 Daubert* ruling. Plaintiff agrees. *See* Response at 9. The Court concurs that Lembke may not opine that pharmacies “failed to provide pharmacists with sufficient time, resources, or incentives to investigate red flags.” CT3 Daubert Order re: Lembke at 13 (docket no. 3953) (quoting CT3 Lembke Report at 8). This opinion is beyond her expertise.

Kroger further asserts the *Track 3 Daubert* ruling also precludes some of Lembke’s detailed statements supporting her sixth opinion. Specifically, Kroger points to Lembke’s statement that “Pharmacy Defendants failed to adequately respond to ‘red flags’ for misuse and diversion *or support individual pharmacists in these efforts[.]*” Motion at 5-7 (quoting CT7 Lembke Report at 142). Kroger contends the italicized portion of this statement, *i.e.* that pharmacies failed to support individual pharmacists’ efforts to prevent opioid misuse and diversion, is merely a restatement of her precluded opinion that the pharmacies failed to provide pharmacists with sufficient time and resources to investigate red flags. Reply at 10 (docket no. 4964).

Plaintiff responds that Lembke may appropriately testify regarding the pharmacies’ response to red flags. The Court generally agrees with this statement.<sup>26</sup> However, Plaintiff’s

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<sup>25</sup> Lembke states the pharmacies engaged in coordinated efforts that included, *inter alia*, direct mailings and media campaigns to patients, continuing medical education courses for pharmacists, and creating “Super Stores” where prescription opioids were readily available and abundant. CT7 Lembke Report at 100 (docket no. 4889-1).

<sup>26</sup> *See, e.g.*, CT3 Daubert Order re: Lembke at 12-13 (Lembke is well-qualified to opine on the efficacy and effects of many of Defendants’ policies and procedures, including Defendants’ “alleged ignoring of ‘red flags’ for misuse and diversion including concerns expressed by their own pharmacists”) (quoting CT3 Lembke Report at 8) (emphasis omitted)); CT3 Order Denying JMOL at 60-61 (docket no. 4295) (Lembke’s *Track 3* trial testimony regarding alleged

response does not address Kroger's assertion that Lembke may not opine the pharmacy defendants *failed to support individual pharmacists* in their efforts to respond to red flags. *See* Response at 9-12. The Court agrees with Kroger that this particular statement addresses internal workplace rules for pharmacists, which this Court has concluded is outside Lembke's area of expertise.

In *Track 3*, the Court found Lembke's expertise did not extend to *every* pharmacy policy or procedure. For example, the Court found: "[n]othing in Lembke's background provides her a basis upon which to assess whether a Pharmacy sufficiently incentivized its pharmacist-employee to investigate a 'red flag.'" CT3 Daubert Order re: Lembke at 13 (docket no. 3953). The Court concluded: "Lembke may properly opine that pharmacists should examine prescriptions for 'red flags,' and that failing to do so leads to misuse and diversion, but it is outside of her area of expertise to assert that internal workplace rules applicable to pharmacists precluded a 'red flag' examination." CT3 Daubert Order re: Lembke at 13 (docket no. 3953). As such, while Lembke may properly testify that Defendants' policies and procedures were inadequate to detect certain "red flags," she may not opine that pharmacies failed to "support individual pharmacists" in their efforts to respond to red flags for misuse and diversion.

Kroger also urges the Court to exclude "any related opinions . . . for the same reasons," but provides no specific examples of additional opinions it seeks to exclude. Motion at 6 (docket no. 4889). The Court declines to sift through the 107 pages of detailed statements supporting Lembke's sixth opinion. In the context of trial, Kroger may object if any particular opinions fall outside of Lembke's expertise, as set forth here and in the Court's prior orders.

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inadequacies in the pharmacy defendants' policies and procedures to detect red flags that were well-known in the medical community "fell squarely within the scope of her extensive medical knowledge and expertise").

### III. Courtwright

David T. Courtwright, Ph.D., is a Presidential Professor Emeritus in the Department of History of the University of North Florida. According to his Report, Courtwright “remains active in research and scholarly refereeing and is an internationally recognized authority on the history of drug use and drug policy.” T7 Courtwright Report at 3 (docket no. 4889-2).<sup>27</sup>

In *Track 7*, Courtwright offers opinions spanning 395 pages on a broad range of topics including, *inter alia*: (1) a “revisionist campaign against narcotic conservatism crystallized in the early-to-mid 1980s” based on published research that “mischaracterized historical experience with narcotics . . . and relied on evidence that understated . . . the long-term risks of outpatient opioid treatment for [chronic nonmalignant pain (CNP)];” (2) opioid manufacturers (including Purdue and others) “took advantage of this shifting climate of medical opinion, which they had helped to direct and engineer, to aggressively market opioid painkillers for CNP;” (3) “[n]ational pharmacies assisted manufacturers by promoting branded opioid products and by arranging for their pharmacists to receive manufacturer-sponsored pro-opioid educational materials and to participate in manufacturer-sponsored continuing education programs;” (4) despite the emergence of the addiction and overdose crisis in the early 2000s and warnings from the DEA, opioid distributors failed to report and/or stop suspicious orders; (5) “[n]ational pharmacies compounded the diversion problem by continuing to fill suspicious opioid prescriptions, despite detailed warnings from law enforcement and from their own employees;” and (6) “[t]hese supply-control derelictions occurred in Ohio and other states, including Florida, whence large quantities of painkillers were

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<sup>27</sup> Courtwright’s list of publications includes multiple books that “describe drug use and drug policy in relation to U.S. social and political history,” along with drug-related articles appearing in the *New England Journal of Medicine* and other journals. *Id.*; David T. Courtwright, Curriculum Vitae, Appx. A to CT7 Courtwright Report (docket no. 4889-2).

diverted into Ohio and nearby states.” CT7 Courtwright Report at 8-11 (docket no. 4889-2) (summarizing his opinions).

Kroger seeks to exclude Courtwright’s opinions on pharmaceutical marketing causation “to the extent they violate Orders previously entered by the Court in prior MDL tracks.” Motion at 1, 7 (docket no. 4889). Specifically, Kroger challenges Courtwright’s opinions that:

National pharmacies [including Kroger] assisted manufacturers by promoting branded opioid products and by arranging for their pharmacists to receive manufacturer-sponsored pro-opioid educational materials and to participate in manufacturer-sponsored continuing education programs. . . . [and] compounded the diversion problem by continuing to fill suspicious opioid prescriptions, despite detailed warnings from law enforcement and from their own employees. . . . whence large quantities of painkillers were diverted into the illicit interstate traffic.

Motion at 7 (docket no. 7889) (quoting CT7 Courtwright Report at 10 (docket no. 4889-2)).

Additionally, Kroger objects to the concluding paragraph of Courtwright’s Report, which states, in part:

[N]ational pharmacies all played multiple roles in that campaign [“to subvert narcotic conservatism and the strict regulatory regime with which it was associated”]. The common, intended effect of their efforts was to substantially increase exposure to prescription opioids, despite their known addictive and toxic properties. The result of that exposure was that Ohioans and other Americans endured a second prolonged epidemic of medicinal opioid addiction.

*Id.* (quoting CT7 Courtwright Report at 395 (docket no. 4889-2)).

Kroger’s motion to exclude Courtwright’s marketing causation opinions is based almost entirely on generic references to previous orders entered in the MDL. In particular, Kroger argues Courtwright’s opinions should be excluded based on the Court’s prior *Track 3 Daubert* order regarding Lembke (docket no. 3953, discussed above). *Id.* at 7-8. However, Kroger provides no discussion or analysis to show how or why the Court’s previous orders – or its prior analysis regarding Lembke – should apply to preclude Courtwright’s opinions. Instead, Kroger merely cites the *Track 3 Daubert* order and conclusorily asserts: “Courtwright, a historian, is no more qualified

than Lembke to offer an opinion regarding a causal connection with respect to pharmaceutical marketing.” *Id.* at 7-8 (docket no. 4889) (quotations and citation omitted).

Plaintiff responds that Kroger’s motion improperly attempts to extend the Court’s previous *Daubert* rulings regarding Lembke to a different expert, Courtwright. The Court agrees. The Court’s previous rulings addressed Lembke’s qualifications, as a medical expert, to opine on the effects of pharmaceutical marketing. That analysis does not inevitably or necessarily apply to marketing causation opinions expressed by other experts. As discussed above, the Court’s prior rulings focused on Lembke’s particular expertise, both as a practicing physician and as a distinguished academic on opioid prescribing and the history and origins of the opioid epidemic. *See* CT3 Order Denying JMOL at 62 (docket no. 4295). Moreover, after hearing her *Track 3* trial testimony, the Court found Lembke was “well qualified” to opine that misleading marketing activities by opioid manufacturers, distributors, and pharmacies created a “paradigm shift” in opioid prescribing, thereby creating an oversupply of prescription opioids that led to the opioid epidemic. *Id.* at 61-62 (citations omitted). Kroger’s argument that Courtwright is no more qualified than Lembke, therefore, does not do it much good.

And, as Plaintiff correctly points out, this Court has not previously ruled on Courtwright’s qualifications or the admissibility of his opinions. As an historian, Courtwright has formed his opinions based on a different expertise, and from a different perspective, than Lembke. Kroger’s motion does not address how the Court’s previous analysis regarding Lembke applies to Courtwright’s qualifications to express his opinions.

In its reply brief, Kroger for the first time asserts that a *Track 2* ruling by the transferor court, on remand, operates to preclude Courtwright from expressing his opinions in *Track 7*. Reply at 3-4 (docket no. 4964). Kroger cites a memorandum opinion and order entered by the Honorable



David A. Faber in the Southern District of West Virginia addressing the admissibility of six expert reports, including Courtwright's. Reply at 3-4 (docket no. 4964) (citing CT2 Daubert Order at 2 (docket no. 1262 in S.D. W.Va. Case Nos. 3:17-01362 and 3:17-01665)).<sup>28</sup> But in that order, Judge Faber did not address Courtwright's specific opinions or qualifications. Instead, Judge Faber discussed examples of opinions offered by *other* experts and announced "ground rules" that generally prohibited admission of the following categories of expert testimony in the *Track 2* trial: (1) lengthy testimony that merely restates factual information found in documents; (2) testimony regarding defendants' motive, intent, and/or state of mind; and (3) testimony regarding defendants' corporate ethics, responsibilities, and/or duties.<sup>29</sup> CT2 Daubert Order at 2 at 10.

As a preliminary matter, the Court declines to address arguments raised for the first time in a reply brief. *See* CT1-B MSJ Order re: Walmart at 4 n.12 (docket no. 3102)<sup>30</sup> (citing *Ross v. Choice Hotels Int'l, Inc.*, 882 F. Supp.2d 951, 958 (S.D. Ohio 2012) ("a reply brief is not the proper place to raise an issue for the first time")). Moreover, Judge Faber's opinion does not support Kroger's position that any specific opinion of Courtwright should be excluded; his opinion merely sets salutary guidelines for eliciting testimony at trial.<sup>31</sup>

Finally, in its reply, Kroger for the first time makes a stand-alone argument – *i.e.*, not based on the Court's prior rulings – that Courtwright is not qualified to opine on pharmaceutical marketing. *See* Reply at 4-6 (docket no. 4964). But this argument is unsupported. Kroger's motion

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<sup>28</sup> *City of Huntington v. AmerisourceBergen Drug Corp.*, 2021 WL 1320716 (S.D. W.Va. April 4, 2021).

<sup>29</sup> In its reply brief, Kroger conclusively asserts that, in addition to the "one example" of improper marketing causation opinion cited in its motion, the Court should also exclude "other opinions" by Courtwright that "violate any of the other three categories of impermissible testimony [identified by Judge Faber in *Track 2*]." Reply at 3-4 (docket no. 4964). Kroger provides no specific examples or citations to any such "other opinions."

<sup>30</sup> *In re Nat'l Prescription Opiate Litig.*, 2020 WL 425965, at \*2 n.12 (N.D. Ohio Jan. 27, 2020).

<sup>31</sup> The *Track 2* order provides no analysis regarding Courtwright's opinions, and Kroger makes only conclusory arguments and provides no analysis or discussion as to how or why Judge Faber's reasoning should apply to preclude the specific opinions offered by Courtwright in *Track 7*. *See* Reply at 3-4 (docket no. 4964).

does not independently challenge Courtwright's qualifications; it contains no discussion of Courtwright's experience; it sets forth no analysis regarding the substance of his opinions; and it does not discuss how those opinions relate to his stated expertise.<sup>32</sup> Because Kroger's motion does not independently challenge whether Courtwright is qualified to express the opinions offered in his *Track 7* Report, it provides no basis for exclusion. Accordingly, the Court denies Kroger's motion to exclude portions of Courtwright's *Track 7* Report based on its prior MDL rulings.

#### IV. James Rafalski

James Rafalski is a former DEA Investigator who offers opinions regarding the necessary components of a system designed to maintain effective controls for preventing diversion of controlled substances. Among other things, his *Track 7* Report discusses various standards and guidelines regarding a registrant's duty to maintain effective controls against diversion of prescription opiates, and "key components that one would expect to see in an operational system designed to maintain effective controls against diversion." CT7 Rafalski Report at 8-42 (docket no. 4889-3).

Kroger contends Rafalski's *Track 7* Report contains improper legal opinions that "explicitly violate" the Court's prior *Daubert* rulings in *Track 1* and *Track 3*. Motion at 8 (docket no. 4889). Specifically, Kroger asserts Section III.L of Rafalski's Report improperly renders a "legal interpretation" regarding what constitutes an inadequate SOMS system under 21 C.F.R.

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<sup>32</sup> Only one page of Kroger's motion addresses Courtwright's opinions. *See* Motion at 7-8. Half of this page contains block quotes from Courtwright's Report, as stated above. The remainder is comprised of four sentences: (1) "Courtwright, like Lembke, improperly proffers an opinion concerning marketing causation;" (2) his opinions arise "from nothing but a historical review of literature on the opioid epidemic coupled with sparse information implicating Kroger;" (3) "Courtwright, a historian, is no more qualified than Lembke to offer an opinion regarding a causal connection with respect to pharmaceutical marketing;" and (4) "any such conclusory opinions should be excluded." *Id.* (quotations and citations omitted). These arguments are insufficient to raise an independent *Daubert* challenge to Courtwright's qualifications and/or the opinions stated in his Report.

§ 1301.74(b). Motion at 9 (docket no. 4889). Kroger urges the Court to exclude Section III.L, in its entirety.

### **A. Prior *Daubert* Rulings**

In *Track 1*, the Court found “Rafalski clearly has experience and expertise regarding the components and characteristics he would expect to be included in an effective [suspicious order monitoring system (“SOMS”)] and due diligence program.” CTI Daubert Order re: Rafalski & McCann at 8 (docket no. 2494).<sup>33</sup> However, the Court also ruled that, “to the extent Rafalski expresses opinions as to what the law requires, or whether Defendants’ conduct violated the law, his opinions are not admissible.” *Id.*

In *Track 3*, the Court reaffirmed its *Track 1* ruling, stating Rafalski could offer opinions regarding whether, in his experience, “a SOMS is effective if it has or does not have certain characteristics.” CT3 Daubert Order re: Rafalski at 7 (docket no. 3929).<sup>34</sup> However, the Court found the *Track 3* Report went “well beyond that” and offered “many legal opinions and ultimate legal conclusions” regarding whether a particular defendant’s conduct violated the law.<sup>35</sup> *Id.* The Court nevertheless noted that some of Rafalski’s legal statements accurately reflected the law (as instructed by the Court and the plain language of the statutes and regulations), to which he could

<sup>33</sup> *In re Nat’l Prescription Opiate Litig.*, 2019 WL 3934490 (N.D. Ohio Aug. 20, 2019).

<sup>34</sup> *In re Nat’l Prescription Opiate Litig.*, 2021 WL 3917174 (N.D. Ohio Sept. 7, 2021).

<sup>35</sup> More specifically, the Court cited the following examples of improper legal opinions or conclusions by Rafalski in *Track 3*: (1) Defendants’ inadequate due diligence constitutes a failure to comply with CSA requirements; (2) CVS failed to maintain effective controls in violation of 21 U.S.C. § 823(b)(1); (3) Walgreens failed to design and operate a SOMS in violation of 21 C.F.R. § 1301.74(b); (4) Walgreens’ conduct in cutting orders without reporting them to the DEA as suspicious did not comply with its CSA obligations; (5) Rite Aid, Walmart, and Giant Eagle failed to maintain effective controls in violation of 21 U.S.C. § 823(b)(1) and failed to design and operate a SOMS in violation of 21 C.F.R. § 1301.74(b)). CT3 Daubert Order re: Rafalski at 7 (docket no. 3929) (citing specific pages of Rafalski’s *Track 3* Report).

permissibly refer, “especially to provide background and context for his SOMS and due diligence opinions.” *Id.*

## **B. Analysis**

Section III.L of Rafalski’s Report consists of one paragraph stating, in part, as follows:

### **L. DEA CHEMICAL HANDLER’S MANUAL**

Walgreens and [other registrants, like Kroger,] have relied on the DEA’s Chemical Handler’s Manual . . . as guidance provided by the DEA regarding its suspicious order monitoring system for Schedule II and III controlled substances, including prescription opiates. It is worth noting that these guidelines relate to “Listed Chemicals”, rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. “Suspicious orders” of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of “extraordinary” size [based on a formula which generally multiples [sic] a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.

Relying upon a threshold of “extraordinary” size fails to detect orders of “unusual size” and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

CT7 Rafalski Report at 37 (docket no. 4889-3).<sup>36</sup>

Kroger asserts that, in Section III.L, Rafalski is improperly “comparing” and “conflating” different legal definitions and requirements and rendering a “legal interpretation” of what constitutes an inadequate SOMS under 21 C.F.R. § 1301.74(b). Motion at 8, 9 (docket no. 4889).

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<sup>36</sup> In *Track 1* and *Track 3*, Rafalski’s Reports contained nearly identical sections. See CT1 Rafalski Report at 36 (docket no. 1900-2); CT3 Rafalski Report at 39-40 (docket no. 4219-13) (same). However, neither the *Daubert* motions nor the Court’s prior orders specifically addressed those opinions.

Plaintiff responds that Section III.L does not contain an improper legal conclusion; rather, Rafalski simply expresses his opinion, based on his experience as a DEA agent, that the requirements for Listed Chemicals are different than the requirements for Controlled Substances. Response at 5-6 (docket no. 4946).

Upon close review, the Court agrees with Plaintiff that Kroger has not shown the opinions expressed in Section III.L are improper. Of particular note, Kroger does not contend the section contains any *misstatements* of law. As the Court found in *Track 3*, Rafalski may permissibly refer to accurate legal statements “to provide background and context for his SOMS and due diligence opinions.” CT3 Daubert Order re: Rafalski at 7 (docket no. 3929).

Ultimately, the opinions in Section III.L suggest that a SOMS incorporating *only* the “extraordinary” size threshold of 21 U.S.C. § 830(b)(1)(A) would not detect *all* types of “suspicious orders,” as defined by 21 C.F.R. § 1301.74(b).<sup>37</sup> Although Rafalski arguably uses legal terminology by stating such a system would not be “compliant” with 21 C.F.R. § 1301.74(b), he stops short of saying Kroger (or any registrant) relied *solely* on the “extraordinary” size threshold or otherwise violated the law. *Cf.* CT3 Daubert Order re: Rafalski at 7 (docket no. 3929) (citing specific examples of improper legal opinions and ultimate legal conclusions regarding whether a particular defendant’s conduct complied with certain legal requirements). In this context, Rafalski’s opinions appear to fall within the scope of his experience and expertise as a former DEA Inspector.<sup>38</sup> In other words, so long as he applies correct legal standards, as defined by this Court

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<sup>37</sup> Section 1307.74(b) states that “suspicious orders” include “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

<sup>38</sup> See CTI Daubert Order re: Rafalski & McCann at 2-4 (docket no. 2494) (as a DEA Investigator, Rafalski conducted regulatory investigations to determine registrants’ compliance with DEA requirements regarding SOMS).

and set out in applicable statutes and regulations, Rafalski may permissibly opine whether a SOMS designed to flag only “extraordinary” size orders would effectively detect “suspicious orders.”<sup>39</sup>

On this record, the Court declines to strike the opinions found in Section III.L or elsewhere in Rafalski’s *Track 7* Report.<sup>40</sup> In the context of trial, defendants may object if Rafalski’s proffered testimony crosses the line of “well-established legal principles generally prohibiting experts from opining as to what the law requires, or whether Defendants’ conduct violated the law.” CT3 Daubert Order re: Rafalski at 7 (docket no. 3929).

## V. Conclusion.

For the foregoing reasons, Kroger’s Motion to Exclude Portions of the Opinions Offered by Dr. Anna Lembke, David Courtwright, and James Rafalski (docket no. 4889) is **GRANTED in part**. Regarding part of her sixth opinion, Anna Lembke, M.D., may not opine that pharmacies “failed to provide pharmacists with sufficient time, resources, or incentives to investigate red flags,” or that pharmacies failed to “support individual pharmacists” in their efforts to respond to red flags for misuse and diversion.

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<sup>39</sup> See CTI Daubert Order re: Rafalski & McCann at 8 (docket no. 2494) (“Rafalski clearly has experience and expertise regarding the components and characteristics he would expect to be included in an effective [SOMS] and due diligence program.”); see also Fed. R. Evid. 702 (a witness may testify as an expert if, *inter alia*, his testimony “relates to matters beyond the knowledge or experience possessed by lay persons”).

<sup>40</sup> Kroger also seeks to exclude opinions throughout the Report “to the extent they contain legal conclusions or interpretations of law.” Motion at 9 (docket no. 4889). Other than Section III.L, Kroger provides no specific examples of legal opinions it seeks to exclude. The Court declines to sift through the entire Report to identify potentially impermissible opinions. See CT3 Daubert Order re: Rafalski at 7 (docket no. 3929).

Kroger's Motion to Exclude Portions of the Opinions Offered by Dr. Anna Lembke, David Courtwright, and James Rafalski (docket no. 4889) is otherwise **DENIED**.

**IT IS SO ORDERED.**

/s/ Dan Aaron Polster May 5, 2023  
**DAN AARON POLSTER**  
**UNITED STATES DISTRICT JUDGE**